

National Cancer Institute
Institutional Review Board

AGENDA
January 12, 2015
1:00 – 5:30 pm
10 CRC/3-1608

- 1. Review of Draft Minutes, December 15, 2014**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
 - NIH Policy on Genomic Data Sharing
 - NIH IRP Working Group on Incidental Findings
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Response to Stips** 11C0266-K, "A Phase I/II Study of the Safety and Feasibility of Administering T Cells Expressing Anti-EGFRvIII Chimeric Antigen Receptor to Patients with Malignant Gliomas Expressing EGFRvIII" - Steve Rosenberg, PI
- 9. Response to Stips** 12C0113-E, "A Phase I Study of a Continuous Intravenous Infusion of Recombinant Human Interleukin IL-15 (rhIL-15) in Adults with Metastatic Cancers" - Kevin Conlon, PI
- 10. Response to Stips** 10C0066-E, "Collection of Human Samples to Study Hairy Cell and Other Leukemias and to Develop Recombinant Immunotoxins for Cancer Treatment" - Robert Kreitman, PI
- 11. Response to Stips** P141751, "A Pilot Study of an Integrated Imaging Strategy to Phenotype Progression of HCC Tumors during and after Chemoembolization" - Elliot Levy, PI
- 12. Response to Stips** P121083, "A Randomized, Placebo-Controlled Phase II Study of Multi-Epitope TARP Peptide Autologous Dendritic Cell Vaccination in Men with Stage D0 Prostate Cancer" - Lauren Wood, PI
- 13. Response to Stips** P131334, "A Pilot Study of Long Term TARP Vaccination Using A Multi-Epitope TARP Peptide Autologous Dendritic Cell Vaccine in Previously Vaccinated Men on NCI 09-C-0139 " - Lauren Wood, PI
- 14. Amendment** 11C0191-M, "A Phase 1 and Phase II Study of AZD6244 for Recurrent or Refractory Pediatric Low Grade Glioma" - Kathy Warren, PI
- 15. Amendment** 11C0160-I, "A Pilot/ Phase II Study of Pentostatin Plus Cyclophosphamide Immune Depletion to Decrease Immunogenicity of SS1P in Patients with Mesothelioma, Lung Cancer or Pancreatic Cancer" - Raffit Hassan, PI

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| 16. Amendment | 10C0086-F, "Comprehensive Omics Analysis of Pediatric Solid Tumors and Establishment of a Repository for Related Biological Studies" - Rosandra Kaplan, PI |
| 17. Amendment | 93C0133-WW, "Dose-Adjusted EPOCH Chemotherapy and Rituximab (CD20+) in Adults and Children with Previously Untreated Patients with Aggressive Non-Hodgkin's Lymphoma" - Wyndham Wilson, PI |
| 18. Amendment | 09C0082-V, "Assessment of the Safety and Feasibility of Administering T cells Expressing an anti-CD19 Chimeric Antigen Receptor to Patients with B-cell Lymphoma or Leukemia" - Steve Rosenberg, PI |
| 19. Amendment | 02C0179-T, "Biospecimen Acquisition from Human Subjects" - James Gulley, PI |
| 20. Amendment | 13C0120-F, "A Pilot Study of Tremelimumab, A Monoclonal Antibody Against CTLA-4 in Combination with Trans-Arterial Catheter Chemoembolization (TACE), Radiofrequency Ablation (RFA), Stereotactic Body Radiation Therapy (SBRT) or Cryoablation in Subjects with Hepatocellular Carcinoma (HCC) or Biliary Tract Carcinomas (BTC)" - Tim Greten, PI |
| 21. Initial Review | P141680, "Randomized Controlled Trial of Total Thyroidectomy with and without Prophylactic Central Neck Lymph Node Dissection in Patients with Low-risk Papillary Thyroid Cancer" - Naris Nilubol, PI |
| 22. Initial Review | P141749, "A Phase I Trial for the Evaluation of the In Vivo Persistence of Adoptively-transferred Tumor-Infiltrating Lymphocytes Cultured with a Pharmacologic Inhibitor of AKT in Patients with Metastatic Melanoma" - Steve Rosenberg, PI |
| 23. Initial Review | P141776, "A Phase II, Open-Label, Multi-Center Study of ANG1005 in Breast Cancer Patients with Recurrent Brain Metastases" - Susan Bates, PI |
| 24. Initial Review | P141640, "Phase I/II Trial of PLX3397 in Children and Young Adults with Refractory Leukemias and Refractory Solid Tumors Including Neurofibromatosis Type 1 (NF1) Associated Plexiform Neurofibromas" - Rosandra Kaplan, PI |
| 25. Initial Review | P131445, "A Phase 1, Open-label, Dose-escalation Study of SNX-5422 and Everolimus in Subjects with Neuroendocrine Tumors or Renal Cell Carcinoma" - Arun Rajan, PI |
| 26. Initial Review | P141769, "Phase IA/IB, Open-Label, Multicenter, Multiple Ascending Dose Study Followed by an Extension Phase to Evaluate the Safety, Tolerability, Pharmacokinetics and Activity of RO6927005, an anti-Mesothelin (MSLN) Recombinant Cytolytic Fusion Protein (cFP), Administered Either Alone (Part A) or in Combination with Gemcitabine and NAB-Paclitaxel (Part B) in Patients with Mesothelin-Positive Metastatic and/or Locally Advanced Malignant Solid Tumors" - Raffit Hassan, PI |